National Institutes of Health Small Business Research Grants

Advice On SBIR and STTR Applications

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SBIR – Small Business Innovation Research
 STTR – Small Business Technology Transfer

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EVALUATION FORM

PLEASE Fill out this evaluation form if you use this guide to help you write an SBIR or STTR application. Help us to make the next edition better.

FAX Completed form to (301) 402-0369.

PL	EASE RATE EACH CHAPTER	Not useful				Very useful
	(Place X in appropriate box)	1	2	3	4	5
I.	Rationale for NIH Small Business Grants					
II.	Phase I SBIR and STTR Application					
III.	Review of SBIR and STTR Applications					
IV.	You Have Been Approved for an Award					
V.	Grantee Responsibilities for Invention Reporting					
VI.	Model Agreements					
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Additional Comments:

Optional: Name, organization, address, phone, fax, and email address on cover sheet.

INTRODUCTION AND ACKNOWLEDGMENTS

Advice on SBIR and STTR Applications is an experiment in reinvention. The purpose of this guide is to provide encouragement and mentoring to those applying for NIH small business grants. Please share Advice on SBIR and STTR Applications with your colleagues.

PLEASE NOTE: To help you distinguish objective information from opinion, the rules

and regulations are formatted in regular type and advice and

commentary in bold italics.

You should be aware that the advice and values in this guide may not be shared by everyone, including those who review applications or decide grant award funding. The subjective comments are based on experience of NIH staff and others who generously contributed their knowledge of and experience with the SBIR program. Some of the major contributors are listed below.

NAME	CONTRIBUTION
Joyce Brinton, Director, Harvard University Office for Technology Transfer	Chapter on "Model Agreements Between Academic Institutions and Companies"
JoAnne Goodnight, National Cancer Institute	Suggested revisions and clarifications
Maya Hadar, Special Assistant, Division of Extramural Activities, NIAID	Edited Advice on SBIR and STTR Applications
Mary Kirker, Chief, Grants Management Branch, Division of Extramural Activities, NIAID	Grants management information
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Robert Moore , Office of Extramural Research, Office of the Director, NIH	Data on NIH award numbers and success rates
Sue Ohata, Director, Division of Extramural Inventions and Technology Resources, Office of the Director, NIH	Chapter on "Grantee Responsibilities for Invention Reporting"

The information presented in this guide does not replace instructions in the current SBIR and STTR Omnibus Solicitations. Applicants are encouraged to seek advice from experienced colleagues and from appropriate NIH program staff.

The SBIR and STTR Omnibus Solicitations are the official documents for the preparation of SBIR and STTR grant applications. Any differences between the solicitation instructions and this guide are unintentional. Please let us know If you find discrepancies. We welcome all your comments and suggestions. Please fill out the evaluation form on page 4, and return it by fax.

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I. RATIONALE FOR NIH SMALL BUSINESS GRANTS

Many Benefit From SBIR and STTR

All key players in biomedical research and product development can benefit from NIH small business research grants in these ways.

Small Biotechnology Company

NIH small business grants enable the government to partner with small companies. These grants provide up to \$850,000 in research dollars for innovative projects striving to develop products to benefit public health. Although applying for an NIH grant is a lot of work, as is conforming to Federal regulations, the intellectual property a company develops belongs to it alone with almost no strings attached (see Chapter V).

Further, these grants offer company scientists an opportunity to fund embryonic projects when company support may be unavailable. And they promote and foster partnerships with academic laboratories.

Academic Investigators and Institutions

By serving as a collaborator, consultant, or principal investigator (for STTR), an academic investigator can gain long-term financial and scientific benefits. Collaboration with a company also offers access to company resources and expertise and possibly jobs for graduate students and postdocs.

NIH small business grants can add value to an academic institution's intellectual property. The research and development (R&D) may generate licensing revenue and further partnerships with industry.

Large Pharmaceutical Corporations

With rapidly expanding biological knowledge, even large corporations can develop only a limited number of promising lead ideas. Large pharmaceutical corporations often look to small biotech companies for the initial development of embryonic technology. Thus, the end of a successful project for a small biotech company is often the beginning of R&D for a large pharmaceutical corporation.

NIH small business grants can help bridge the needs of both by providing early-stage funding for research that adds value to an idea, promoting partnerships that lead to a marketable product.

National Institutes of Health

Small business grants support the NIH mission to "manage a portfolio of investments to improve health through science."

They catalyze the transfer of technology from academia to companies by supporting innovative, embryonic research that feeds potential products into the R&D pipeline.

Figure 1 illustrates how this occurs.

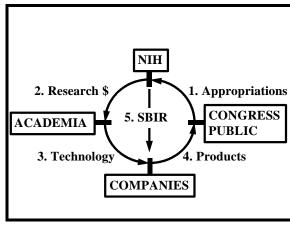


Figure 1. Funds to Products Pathway

- 1. Congress appropriates funds to NIH.
- 2. With these funds, NIH supports research to academic institutions mostly through investigator-initiated grants.
- 3. Resulting new technologies form the basis for new products.
- 4. New health products encourage the public and Congress to continue (and perhaps increase) NIH funding.
- 5. NIH small business grants catalyze technology transfer from academia to companies by supporting innovative, embryonic research.

The Public

Figure 2 shows how the public benefits from NIH small business grants.

- NIH invests over \$12 billion a year in research to increase scientific knowledge. The resulting technology is used by companies to develop products.
- Biotech companies and the pharmaceutical industry spend about \$20 billion on R&D.

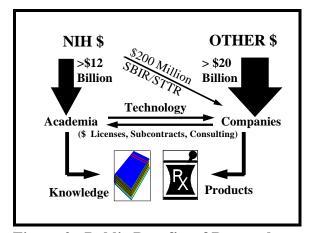


Figure 2. Public Benefits of Research

- Companies also provide money to academic institutions.
- The \$200 million in NIH small business grants catalyzes the development of products from new technology.

Comparison of Small Business and Academic Research Grants

SBIR Value Equals Products

Though small business grants undergo the same rigorous processes of application and review as do academic research grants, they are valued differently. Whereas the value of academic research grants is measured by impact on scientific knowledge, the value of SBIR research is derived from the health and economic benefits of a resulting product.

Bringing an SBIR product to successful commercialization may take many years following the conclusion of Phase II. As illustrated in **Figure 3**, historical data for all

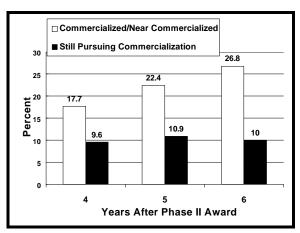


Figure 3. SBIR Results in Commercial Products

Federal agencies awarding SBIR grants show that 27 percent of the projects resulted in product sales within six years of the Phase II award (1992 report from the Small Business Administration Office of Technology). An additional 10 percent are still pursuing commercialization.

Successful commercialization varied greatly by agency, but NIH had the highest percentage of commercialized SBIR projects and the greatest amount of product sales reported by companies receiving SBIR funding.

Success Rates Similar for SBIR and Academic Research Grants

One way of comparing the quality of SBIR grants with academic grants is to compare "success rates." Success rate is the number grants awarded divided by the number applications reviewed, then multiplied by 100. Success rate is a measure of the degree of competition for funds.

Figure 4 shows that the success rate for SBIR Phase I applications is somewhat greater than that for investigator-initiated new research project awards (R01) and somewhat less than that for NIH FIRST awards (R29) to young investigators. Thus, the probability of success

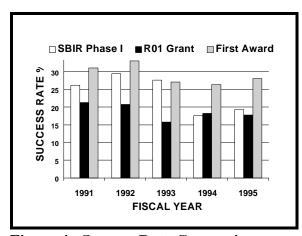


Figure 4. Success Rate Comparisons

for an SBIR application appears to be about the same as that for other NIH research project applications.